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10/660,058	09/11/2003	Craig Heacock	CP245	7280

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,058	HEACOCK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *11-17 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,18 and 20-44* is/are rejected.

7)☒ Claim(s) *18, 43 and 44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/2007; 3/2/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-10, 18 and 20-44 is acknowledged. The traversal is on the ground(s) that there is no serious burden to search and examine both Groups because Group I and II are closely related and examination of Group I will therefore inevitably require searching of subject matter common to all the groups. This is not persuasive because the inventions are distinct, each from the other because while Group I and Group II are related as product and process of use, the product as claimed can be used in a materially different process of using that product. As stated in the previous restriction requirement, the product as claimed can be used in a materially different process of using that product because the product has been used to treat urinary and/or fecal incontinence. Therefore, a serious burden would place on the examiner to search unrelated inventions involving different biological mechanism or pathways of the product resulting in different effects. The searches are not coextensive, particularly, a required non-patent literature search would place a serious burden on the Examiner. Therefore, the restriction requirement made in the previous Office Action is deemed proper and made final.

It is noted that Applicants elect the species of claim 9: a pharmaceutical unit dose consisting essentially of 340mg of modafinil. However, no such election of species requirement made in the previous restriction requirement. Therefore, the election of species voluntarily made by the Applicants is moot.

Claims 11-17, and 19 are withdrawn from consideration since they are non-elected invention.

Claim Objections

Claims 43 and 44 are objected to because of the following informalities: Claims 43 and 44 are duplicate of claims 41 and 42, respectively. Appropriate correction is required.

Claim 18 is objected to because it contains or refers to a "Fig. 3" which is a drawing. The claim may contain chemical and mathematical formulae but shall not contain drawing or flow diagrams. (MPEP 608).

> *37 CFR 1.58. Chemical and mathematical formulae and tables.*
>
> (a) The specification, including the claims, may contain chemical and mathematical formulae, but shall not contain drawings or flow diagrams. The description portion of the specification may contain tables, but the same tables may only be included in both the drawings and description portion of the specification if the application was filed under 35 U.S.C. 371. Claims may contain tables either if necessary to conform to 35 U.S.C. 112 or if otherwise found to be desirable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 20-22, 25-35, 43 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 30 and 31 of U.S. Patent No. 6,919,378 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent encompasses same subject matter of composition comprising modafinil. The difference is the specified dose of modafinil. However, it would have been obvious to one of ordinary skill in the art to formulate modafinil composition taught by the Patent with optimum dosage amounts adjust to any given patient to be treated in order to customize the specific amounts need according to his severity and medical profile of the condition.

Claims 1-10, 20-22, 25-35, 43 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 26 and 35-39 of U.S. Patent No. 6,489,363 B2 of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent encompasses same subject matter of composition comprising modafinil. The difference is the specified dose of modafinil. However, it would have been obvious to one of ordinary skill in the art to formulate modafinil composition taught by the Patent with

optimum dosage amounts adjust to any given patient to be treated in order to customize the specific amounts need according to his severity of the condition.

Claims 1-10, 20-22, 25-35, 43 and 44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8, 10, 11, 14 and 52-60 of copending Application No. 10/155,913. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending application and the instant claims are drawn to same subject matter of composition comprising modafinil. The difference is the specified dosage amount of modafinil and the excipients. However, the amounts of active agents or the excipients to be use are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10, 18 and 20-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 93, 94, 97 and 98 of copending Application No. 10/243,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending application is drawn to same or overlapping percentages of modafinil as recited in instant claims. The difference is the specified dosage amounts in mg of modafinil and the excipients. However, the amounts of active agents or the excipients

to be use are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10, 20-22, 25-35, 43 and 44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 35, 36, 37 and 46-50 of copending Application No. 11/550,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending application and the instant claims are drawn to encompassing or overlapping dosage amount of modafinil as recited in instant claims. The difference is functional language of the composition release two or more amounts of a modafinil compound. However, the amounts of active agents released over period of time is not constant upon the ingestion because the amount depletes over time due to metabolism. Further, the formulation of sustained release or the extended release is obvious because they are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent readily available conventional formulations. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The inactive of "binder" set forth in claim 36 renders the claim indefinite because it depends from claim 35 which is free of magnesium silicate or talc which are well-known in the pharmaceutical art as a binder. Claim 36 is contradicting by adding a "binder" while claim 35 which it depends from is free of a binder (magnesium silicate or talc).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 18, 21, 25, 28, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Laurent (U.S.Patent No. 5,401,776) of record.

Laurent teaches the modafinil-containing medicinal product in a form suitable for oral administration. (column 1, lines 35-40). Laurent teaches the modafinil-containing medicinal product in a single dose of 400mg. (column 2, particularly, Table I and II).

Applicants' recitation of the composition results in a blood profile of modafinil substantially as shown in Fig. 3 would be inherent upon administration of same active agent containing same amount taught by Laurent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 5, 7-10, 20, 22-24, 26, 27, 29, 31-34 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laurent (U.S.Patent No. 5,401,776) of record.

Laurent teaches a medicament containing modafinil for the treatment of urinary and fecal incontinence and urethrovesical and anal sphincteral disorders. (abstract). Laurent teaches the modafinil containing medical product may be provided especially in a form suitable for oral administration. Laurent teaches the modafinil-containing medicinal product in a single dose of 400mg. (column 2, particularly, Table I and II). Laurent also teaches the administered doses may be from 1mg/kg to 100mg/kg and **preferably from 5 to 100mg/kg**. (column 1, lines 35-40).

Laurent does not teach the specified amounts in "mg" of modafinil set forth in claims 2, 3, 5, 7-10, 20, 22-24, 26, 27, 29, 31-34 and 38-44.

However, Laurent teaches preferred amounts to be administered expressed in mg/kg, **5 to 100mg/kg** in a table formulation.

It would have been obvious to one of ordinary skill in the art to formulate medicament containing modafinil within the preferred amounts taught by Laurent because Laurent teaches those preferred amounts are effective for the treatment of urinary and fecal incontinence and urethrovesical and anal sphincteral disorder. One of ordinary skill in the art would have been motivated to employ the amounts with in the preferred range from 5 to 100mg/kg in order to customize the specific dosages required

for the patients to be treated. The specific amounts recited in the instant claims are obvious because they fall within the preferred dosages taught by Laurent for patients' who weights between 50kg to 90kg. Further, the pharmaceutical formulation such as well known tablet formulation is obvious because Laurent teaches that modafinil medicament can be formulated in any form suitable for oral administration. One of ordinary skill in the art would have been motivated to formulate modafinil medicament taught by Laurent in oral tablet formulation in order to achieve most convenient suitable oral formulation well known in the art.

Claims 35, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laurent (U.S.Patent No. 5,401,776) of record as applied to claims 2, 3, 5, 7-10, 20, 22-24, 26, 27, 29, 31-34 and 38-44 above and further in view of Lawyer et al. (US 2003/0171439A1).

Laurent as applied as before.

Laurent does not teach the specific diluents, disintegrants, binder and a lubricant set forth in claims 36 and 37.

Lawyer et al. teach that Applicants' specific diluents, disintegrants, binder and a lubricant set forth in claims 36 and 37 are well known inactive ingredients in modafinil-containing tablets. Lawyer et al. teach, however, those inactive ingredients may be considered undesirable because some people may dislike or be allergic to one or more of these inactive ingredients in the modafinil tablets.

It would have been obvious to one of ordinary skill in the art to modify the content of well-known inactive ingredients of modafinil tablets because those inactive ingredients are well-known to be formulated with modafinil but one or more of the inactive may be disliked or develop allergic reaction to some people. One would have been motivated to customize the inactive content by the patient's allergy profile in order to avoid allergic reaction taught by Laurent. There is a reasonable expectation of successfully elimination one or more of inactive ingredient well known to be formulated with modafinil in order to accommodate some people who dislike or are actually allergic to some of those inactive ingredients.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
March 22, 2007